UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,013	04/28/2005	Koushi Nakano	SAEG153.002APC	1676

20995 7590 04/09/2009

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	**PAPER NUMBER**
1632	

NOTIFICATION DATE	DELIVERY MODE
04/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/533,013	NAKANO ET AL.	
	Examiner	Art Unit	
	MARCIA S. NOBLE	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,24 and 25* is/are pending in the application.

4a) Of the above claim(s) *13-20,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11 and 12* is/are rejected.

7)☒ Claim(s) *7-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-20, 24, and 25 are pending. Claim 7 amended by the response filed, 12/16/2008. Claims 1-12 are under consideration.

Withdrawn Rejection

The rejection of claims 7-10, under 35 U.S.C. 103(a) as being unpatentable over Lang et al (of record; 2000), Keetch et al (of record, 1994), Fulmer et al (of record; 2000), Robinette (of record, 1988), and Royston D (Acta anaesthesiologica Scandinavica 30(7):abstract, 1986), in view of Goto (of record; 1988), as set forth in the Office Action, mailed 9/18/2008 (pp. 6-8), is withdrawn.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 11 and 12, as previously presented, are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over (J. Urol. 152:247-250, 1994; of record), as set forth in the Office Action, mailed 9/18/2008 (pp. 3-5).

Keetch et al disclose mice that develop nonbacterial prostatitis following the injection of ventral prostate homogenate and pertussis toxin into the prostate (p. 248, col 1, par 1 of "RESULTS" section, lines 10-13). Keetch et al discloses that the prostatitis is characterized as have inflammation, edema, and epithelial cell degeneration in the prostate (p. 248, col 1, par 2 of "RESULTS" section, lines 1-4). Keetch et al discloses that the inflammatory process was localized to the lateral and dorsal lobes of the prostate (p. 248, col 1, par 2 of "RESULTS" section, lines 4-5). Keetch et al discloses that examination of other organs harvested including bladder revealed no inflammation (p. 248, col 2, lines 1-4). Therefore, Keetch et al discloses nonbacterial prostatitis animal model comprising the structural elements of prostate tissue damage with no tissue damage to lower urinary tract, more specifically the bladder and urethra.

Keetch et al does not disclose that that the model was produced by injection of HCl as claimed and in fact uses a different method to produce the mouse. However, in considering a product-by-process, if a product is disclosed in the prior art comprising all the structural elements of the claimed product, the product is anticipated by the art regardless of the process by which it is made. Keetch et al discloses a product with all

the structural limitations of the claimed product. Therefore, Keetch et al anticipated the instant product-by-process claims.

The claims are also drawn to a method for screening substances for treating nonbacterial prostatitis using the claimed animal model. Keetch et al discloses that the instant mouse is produced to provide a better model for understanding nonbacterial prostatitis and to identify more effective treatments regiments (p. 247, col 1, par 2, lines 8-12).

"Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (*In re Ludtke*). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972))." "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." See also MPEP 2113.

In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re*

Best, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Therefore, at the time of filing it would have been obvious to an artisan of ordinary skill that the instant mouse disclosed by Keetch et al could be predictably used to identify substances to treat nonbacterial prostatitis as suggested by Keetch et al and as well established in the art with a reasonable expectation of success.

Applicant's arguments filed 12/16/2009 have been fully considered but they are not persuasive. Applicant asserts that the nonbacterial prostatitis animal model is distinct, and, thus novel over the mouse of Keetch because the models are made by different processes (p. 6, par 4, line 1-10 of remarks). This argument is not found persuasive. As previously stated, "Keetch et al does not disclose that that the model was produced by injection of HCl as claimed and in fact uses a different method to produce the mouse. However, in considering a product-by-process, if a product is disclosed in the prior art comprising all the structural elements of the claimed product, the product is anticipated by the art regardless of the process by which it is made. Keetch et al discloses a product with all the structural limitations of the claimed product. Therefore, Keetch et al anticipated the instant product-by-process claims."

Applicant asserts that Keetch merely discloses that the examination of other harvested organ – seminal vesicles, testis, coagulation gland, bladder, lungs, and liver – revealed no inflammation and that Keetch et al is silent as to whether or not urethra tissue damage occurred (p. 6, last par, lines 1-4 of remarks). Applicant's arguments are not found persuasive. As previously discussed, Keetch et al discloses that the inflammatory process was localized to the lateral and dorsal lobes of the prostate (p. 248, col 1, par 2 of "RESULTS" section, lines 4-5). Keetch et al discloses that examination of other organs harvested including bladder revealed no inflammation (p. 248, col 2, lines 1-4). From these disclosures, an artisan would understand that inflammation was only present in the prostate because "localized to the lateral and dorsal lobes of the prostate" means that the inflammation was not present in other areas. Thus, while Keetch et al does not literally address the urethra, the disclosure that the inflammation was localized to the prostate implicitly discloses that the inflammation was not present in the urethra. Further this is supported by the observation of no inflammation was present urogenital tissues examined (i.e. testis, seminal vesicles, bladder, and coagulation gland).

Applicant asserts that the model disclosed by Keetch develops an autoimmune prostate inflammation. In contrast, the animal model of the instant invention exhibit severe fibroblast hyperplasia, fibrosis in the interstitium of the prostate, inflammatory cellular infiltration, exhibits pollakiuria, reduced effective bladder capacity, and residual urine (p. 7, par 1, lines 1-11 of remarks). Applicant's argument is not found persuasive. While it may be the intent of applicant to claim an animal model comprising severe

fibroblast hyperplasia, fibrosis in the interstitium of the prostate, inflammatory cellular infiltration, and residual urine, these structural limitations are not present in the claims and therefore are not required to meet the limitations of the claims. Further, claim 3 recites, "wherein the lower urinary disorder is a urine storage disorder posing at least one symptom selected form the group consisting of pollakiuria, urinary incontinence, and reduced effective bladder capacity". This recitation refers "prostate tissue damage characteristically observed in human chronic nonbacterial prostatitis and a lower urinary tract disorder…". Thus the recitation of "pollakiuria, urinary incontinence, and reduced effective bladder capacity" are not structural limitations of the claims but rather inherent consequences of prostate tissue damage, as claimed. In the instant case the only structural limitations present in the claim are an animal with prostate tissue damage with no tissue damage in the urethra and bladder and thus consequently serve as models. If applicant intents for these symptoms to be structural limitations in the claims, applicant must amend the claims to recite these symptoms as clear structural limitations in the animal model and not merely a symptom of the disease that the animal is intended to model. Thus, Applicant's arguments are not found persuasive because, as written, the claims do not require above limitations that Applicant asserts distinguishes the claimed animal model from the art of Keetch.

Therefore, the instant rejection is maintained because Applicant's arguments were not persuasive and the disclosure of Keetch et al still encompasses the limitations of the claims. Should applicant feel there is a structural difference between the animals of Keetch and those claimed, a declaration should be filed identifying the structural

differences. None are apparent from a comparison of the animals of Keetch and those of the claims. It would appear that the same product claimed is produced by Keetch although by a different method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Allowable Subject Matter

Claims 7-10 are objected to as referring to a rejected claim, but would be allowable if rewritten to include all of the limitations of the rejected claim and any intervening claims.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632

Marcia S. Noble
AU 1632